ADVENTRX PHARMACEUTICALS INC
Form 8-K
January 14, 2008

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): January 14, 2008

ADVENTRX Pharmaceuticals, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32157**	**84-1318182**
(State or Other Jurisdiction of Incorporation)	(Commission File No.)	(IRS Employer Identification No.)

6725 Mesa Ridge Road, Suite 100
San Diego, CA 92121
(Address of Principal Executive Offices and Zip Code)

N/A
(Former name or former address if changed since last report)

Registrant s telephone number, including area code: **(858) 552-0866**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 8.01. Other Events.

On January 14, 2008, ADVENTRX Pharmaceuticals, Inc. issued a press release announcing safety results from its marketing-enabling bioequivalence clinical study of ANX-530 (vinorelbine emulsion) and that it intends to submit to the U.S. Food and Drug Administration (FDA) a Section 505(b)(2) New Drug Application (NDA) for ANX-530 in the fourth quarter of 2008, as well as hold a pre-NDA meeting with the FDA in the second quarter of 2008. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The list of exhibits called for by this Item is incorporated by reference to the Index to Exhibits filed with this report.

Forward-Looking Statements

Certain statements in this Form 8-K and the attached press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the safety of ANX-530 and the timeframe in which it intends to submit to the FDA a Section 505(b)(2) NDA for ANX-530. Actual events or results may differ materially from our expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, but are not limited to: the risk of investigator bias in reporting adverse events as a result of the study s open-label nature, including bias that increased the reporting of adverse events associated with Navelbine® and/or that decreased the reporting of adverse events associated with ANX-530; the risk the FDA will determine that ANX-530 and Navelbine are not bioequivalent, including as a result of performing pharmacokinetic equivalence analysis based a patient population other than the population on which ADVENTRX based its analysis; difficulties or delays in manufacturing, marketing and obtaining regulatory approval for ANX-530, including validating commercial manufacturers and suppliers and the potential for automatic injunctions regarding FDA approval of ANX-530 and other challenges by patent holders during the Section 505(b)(2) process; the risk that ADVENTRX will be unable to raise sufficient capital to fund the projects necessary to meet its goals, including funding the continued development and commercialization of ANX-530; the potential for regulatory authorities to require additional preclinical work or other clinical requirements to support regulatory filings; patent and non-patent exclusivity covering Navelbine; ADVENTRX s lack of long-term agreements with suppliers of ANX-530 components and contract manufacturers of ANX-530, including its inability to timely secure commercial quantities of ANX-530 or its components on commercially reasonable terms, or at all; uncertainty under Section 505(b)(2) resulting from legal action against the FDA and the potential that future interpretations of Section 505(b)(2) could delay or prevent the FDA from approving any Section 505(b)(2) NDA; and other risks and uncertainties more fully described in ADVENTRX s press releases and periodic filings with the Securities and Exchange Commission. ADVENTRX s public filings with the Securities and Exchange Commission are available at http://www.sec.gov.

You are cautioned not to place undue reliance on these forward-looking statements, which speak

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only as of the date when made. ADVENTRX does not intend to revise or update any forward-looking statement set forth in this press release to reflect events or circumstances arising after the date on which it was made.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

ADVENTRX Pharmaceuticals, Inc.

Dated: January 14, 2008

By: /s/ Evan M. Levine

Name: Evan M. Levine
Title: Chief Executive Officer

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INDEX TO EXHIBITS

99.1 Press release, dated January 14, 2008